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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,630	04/14/2005	Kevin L. Hodge	18030-PCTUS	8412
7590		12/22/2008		
Lewis J. Kreisler Legal Department 930 Clopper Road Gaithersburg, MD 20878			EXAMINER	
			CARR, DEBORAH D	
			ART UNIT	PAPER NUMBER
			1621	
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			12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/531,630	<b>Applicant(s)</b> HODGE ET AL.
	<b>Examiner</b> DEBORAH D. CARR	Art Unit 1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 05 September 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 14-19,22,25-33 and 43-51 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 14-19,22,25-33 and 43-51 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date See Continuation Sheet

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date 9/07, 10/07, 5/08  
5/08, 7/08, 8/08.

**DETAILED ACTION**

***Response to Arguments***

1. Applicant's arguments, see page 10, filed 5 September 2008, with respect to claims 6, 10-14, 18-19, 27, 32-34, 39-41 have been fully considered and are persuasive. The rejection under 35 USC§102(b) of claims 6, 10-14, 18-19, 27, 32-34, 39-41 and has been withdrawn.
2. Applicant's arguments, see page 10, filed 5 September 2008, with respect to claims 6-13 and 34-41 have been fully considered and are persuasive. The rejection under 35 USC§112, 2<sup>nd</sup> paragraph of claims 6-13 and 34-41 has been withdrawn.
3. Applicant's arguments, see pages 16-20, filed 5 September 2008, with respect to claims 6-19, 22, 24-41 have been fully considered and are persuasive. The rejection under 35 USC§112, 1st paragraph of claims 6-19, 22, 24-41 has been withdrawn.
4. Applicant's arguments filed 5 September 2008 regarding the Provisional Double Patenting rejections of claims 14-15, 17-19, 22-28, 30-33 have been fully considered but they are not persuasive. The rejections will be maintained until the claims of '489 have been amended or cancelled and the application as been deemed allowed.
5. Applicant's arguments, see pages 10-16, filed 5 September 2008, with respect to the rejection(s) of claim(s) 4-15, 17-19, 22-28, 30-33 under 35

USC§102(b)/103 in view of WO'255 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Thorne et al. (US Pat. 4,098,816) and WO 01/36365.

***Double Patenting***

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 4-15, 17-19, 22-28, 30-33 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-33 of copending Application No. 11/841,489. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or

would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 19, 22, 26 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 & claims 1, 6-7, 9-10, 15, 22-23 of copending Application Nos. 11/844,431 & 11/844,432 respectfully. Although the conflicting claims are not identical, they are not patentably distinct from each other because all three applications read on compounds of the same base structure, which can be used to treat metabolic disorders. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Claim Rejections - 35 USC § 102/103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 4-15, 17-19, 22-28, 30-33, 42-51 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thorne (US Pat. 4,098,816).

US'816 teach polycyclic oxy aromatic compounds displaying hypolipidaemic and/or hypoglycemic activity. The compounds can be used in a pharmaceutical composition and administered in unit dosage form within the instant range.

The claims differ from the reference by stating specific substitutions on the substituted carbocyclic compound such as "2, 6-dimethylphenyl." However, it is shown in example 12 in the table bridging cols. 11-12 a compounds wherein the methyl moieties are located on the 2<sup>nd</sup> and 5<sup>th</sup> carbon of the phenyl moiety.

Therefore to modify the substituted carbocyclic (i.e., phenyl) with 2 methyl groups at the 2<sup>nd</sup> & 6<sup>th</sup> position on the phenyl would have been within the skill of one of ordinary skill in the art.

**Conclusion**

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/  
Primary Examiner  
Art Unit 1621

ddc